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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,050	10/05/2005	Lionel Vendrine	P-4604P2	1778
7590 03/30/2009				
David W Highet Becton Dickinson and Company 1 Becton Drive- MC 110 Franklin Lakes, NJ 07417			EXAMINER OSTRUP, CLINTON T	
			ART UNIT 3771	PAPER NUMBER
			MAIL DATE 03/30/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/529,050

Applicant(s)

VENDRINE ET AL.

Examiner

CLINTON OSTRUP

Art Unit

3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 13-25 is/are rejected.
- 7) ☒ Claim(s) 4-12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 March 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1-25 are pending in this application. Claims 13-26 have handwritten amendments.

Drawings

2. The drawings are objected to because Figure 1 is labeled with the term "ABSTRACT". Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The abstract of the disclosure is objected to because it contains two paragraphs. Correction is required. See MPEP § 608.01(b).

Claim Objections

4. Claims 4-12 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.
5. Claims 13-25 are objected to because of the following informalities: Claims 13-25 have handwritten amendments and it is unclear when the amendments were made, who made the amendments, and if claims 1-26 were originally filed or if claims 1-25 were originally filed. Since it is unclear if claims 1-25 were originally filed or if claims 1-26 were originally filed, Applicant is reminded that 37 CFR 1.126 requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
7. Claims 1-3 and 13-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, on page 22, line 38, it is unclear what is meant by "then opposite which comes said nonpressing region" and on page 23, lines 5-7 it is unclear what is meant by "this pressure occurring just before said projection (33) comes opposite said nonpressing region (22)". Claim 1 is also confusing because it refers to "this container", "this movement", "this tab", "this pressure", "this pusher" and "this return" and it is unclear which container, movement, tab, pressure, pusher, and return this claim is referring to. Applicant is respectfully suggested to provide antecedent basis for a term using "a" and then refer back to the term using the terminology "the" or "said".

Claim 2 is also confusing because it is unclear what is being referred to as "this tab", "this end" and "this window."

Claim 2 is confusing because it is unclear what is being referred to as "this travel."

Claim 13 is confusing because it is unclear what is being referred to as "this travel" and "this pusher".

Claim 13 lacks antecedent basis for the term "said piston" on page 26, line 11 and it is unclear if the "piston" is referring to the "plunger" or a different part of the device.

Claim 17 is confusing because it is unclear what is being referred to as "a hollow" on page 28, line 32 and on page 29, line 1.

Claims 19 & 20 are confusing because it is unclear how you "park" a stud. For purposes of examination "park" was read as "place".

Any remaining claims are rejected as depending from a rejected base claim.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-3, as best understood, are rejected under 35 U.S.C. 103(a) as being unpatentable over Borchard (4,962,868) and further in view of Jensen et al. (EP 1129786 A2).

Borchard discloses a spray or injection device (Figure 1) making it possible to deliver at least two preset doses of product (col. 2, lines 10-16), comprising: a container (2) containing the product (liquid pharmaceutical) to be sprayed or to be injected, a plunger (2a) placed in the container which is able to move in the container in order to extract the product from the container, a casing (3a) in which the container is placed, a pusher (3b) which can be moved with respect to the casing to allow the relative movement of the container (2) and of the plunger (2a), means (16) making it possible to subdivide the length of travel of the pusher (3b) with respect to the casing (3a) into at least two travel portions (b & d in figure 3c), each one corresponding to the delivery of a dose of product; the device (figure 1) being characterized in that: the casing (3a) or the pusher (3b) comprises at least one tab (19) which can be moved radially (in relation to 3a) between a first normal radial position (b of figure 3c), in which the tab (19) provides no obstacle to the movement of the pusher (3b) with respect to the casing (3a), and a second radial

position (c of figure 3c), in which the tab (19) provides an obstacle to the movement, the tab (19) comprising a pressing region (the constriction point where 7 contacts 19 and the top of groove 16 on 3b) and a nonpressing region (where 7 does not contact these points).

However, Borchard lacks the pusher or the casing comprising at least one ramp-shaped projection, which the pressing region of the tab presses against during movement of the pusher, with respect to the casing, in a direction that allows the product to be sprayed or injected. Borchard also lacks the teaching of the movement of the pusher, with respect to the casing, along the ramp brings the tab into a second radial position and then to site which comes said nonpressing region of the tab, which allows said tab to return to said first radial position; the pusher or the casing, respectively, further comprises at least one stop region against which the tab presses when it is brought into said second radial position by said projection (33), this pressure occurring just before said projection comes opposite said nonpressing region, the device being designed such that the release of the force exerted on the pusher, which allows the pusher to move with respect to the casing, makes it possible to free the pressure of the tab against said stop region and therefore allows said tab to return to said first radial position, said projection (33) then coming opposite said nonpressing region, this return of said tab (17) to said first radial position making it possible to free the movement of the pusher (5) for a following portion of length of travel, for the purpose of spraying or injecting a following dose of the product.

Jansen teaches a drug delivery device for administering preset doses with a pusher (figure 5) comprising at least one ramp-shaped projection (102), which the pressing region of a tab (76) presses against during movement of the pusher, with respect to the casing (26), in a direction that allows the product to be sprayed or injected. Jensen also teaches movement of the pusher, with respect to the casing, along the ramp brings the tab (76) into a second radial position (figure 7) and then to a nonpressing region of the tab (figure 8), which allows said tab to return to said first radial position (figure 9); the pusher or the casing, respectively, further comprises at least one stop region (figure 9) against which the tab presses when it is brought into said second radial position by said projection (102), this pressure occurring just before said projection comes opposite said nonpressing region, the device being designed such that the release of the force exerted on the pusher, which allows the pusher to move with respect to the casing, makes it possible to free the pressure of the tab against said stop region and therefore allows said tab to return to said first radial position. The projection (102) then coming opposite said nonpressing region, this return of said tab (76) to said first radial position making it possible to free the movement of the pusher (figure 5) for a following portion of length of travel, for the purpose of spraying or injecting a following dose of the product. See: col. 8, [0026] - col. 10, [0031].

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the movement mechanism disclosed by Borchard by utilizing a ramp shaped projection and tab interacting mechanism as taught by Jensen in order to obtain a reliable dose delivery mechanism that requires a minimum

amount of force before activation and provides equal dose of medicament to the nasal passages of a user.

Regarding claim 2, Jensen teaches a one or more windows are provided in the body and the placement of the windows would be a design choice that would provide useful information to the user, such as whether the first dose was administered and/or how much medicament is remaining in the container. See: col. 8 [0025] of Jensen.

Regarding claim 3, Borchard discloses a device comprising at least two tabs (19), two projections (7) and two stop regions (figure 3b), which are diametrically opposed (figure 2).

ALLOWABLE SUBJECT MATTER

10. Claims 13-25 are free of art rejections, but have been objected to for the reasons set forth above and have been rejected under 35 U.S.C. 112, second paragraph.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Porat et al (4,583,978); Korisch et al. (5,951,526); Greiner-Perth (6,382,465); Imbert (5,601,077); Brown et al (2,648,334); Pflieger (4,929,230); and Fuchs (5,427,280) which all disclose hand held metered dose delivery apparatuses.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771